Section 5. 510(k) Summary

AUG 2 2 2006

APPLICANT
[As Required by 21 CFR 807.92 a(1)]

Applicant:	ThermoTek, Inc.
Address:	1454 Halsey Way Carrollton, TX 75007
Telephone Number:	972-242-3232 972-446-1195 (fax)
Company Contact:	Tony Quisenberry President
Date:	June 21, 2006

DEVICE NAME
[As Required by 21 CFR 807.92 a(2)]

Proprietary Name:	NanoTherm™ and VascuTherm™
Common Name:	Intermittent, External Pneumatic Compression Device
Classification Name:	Compressible Limb Sleeve (per 21 CFR section 870.5800)

IDENTIFICATION OF PREDICATE DEVICES
[As Required by 21 CFR 807.92 a(3)]

▪ Chattanooga Group, Inc. PresSsion S III	K942796
▪ KCI PlexiPulse® All-in-1 System	K981311
▪ Aircast VenaFlow System Disposable Cuffs as bundled	K023800
▪ Bio Compression Systems BioComfort Garments	K043423
▪ MicroTek Medical Holdings, Inc. Venodyne DVT Advantage Plus+	K011318
▪ Ormed Artrotherm Cryotherapy and Thermotherapy	K964799 sited and currently exempt Class II, per 21 CFR 890.5720

DEVICE DESCRIPTION
[As Required by 21 CFR 807.92 a(4)]

Intended Use

The NanoTherm and VascuTherm systems are new devices that are intended to function as intermittent, external pneumatic compression devices. The intended therapy of the NanoTherm device is to aid in the reduction and control of edema including lymphedema of the upper and lower extremities and venous stasis ulcers. The intended therapy of the new VascuTherm device is to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding in blood flow back to the heart via lower extremity limb compression in addition to the intended uses of the NanoTherm device.

Physical Description

The NanoTherm device is comprised of a reusable pump (NanoTherm unit) and various single-patient use inflatable wraps (NanoTherm Wraps). The VascuTherm device consists of a reusable pump (VascuTherm unit) and various single-patient use inflatable wraps (VascuTherm Wraps). The VascuTherm unit has additional equipment installed and specially designed wraps specifically for the preventive treatment of DVT.

Therapy Modality Used

The NanoTherm unit thermal control therapy provides chilled fluid and heated fluid to the wrap affixed on an extremity therapy site to reduce pain and swelling and compresses the treatment site for optimum performance and fluid transfer and treatment of edema and lymphedema.

The VascuTherm unit contains a DVT mode that is not present on the NanoTherm unit. This therapy mode is for air-only DVT compression therapy using air-only DVT wraps.

Safety Features

The NanoTherm and VascuTherm systems utilize microprocessor control with multiple sensors to ensure patient safety and system functionality, and to provide consistent and repeatable therapy modalities. Alarms are both visual on the unit display and audible. Alarms are in place to detect a potentially unsafe situation and to terminate therapy to protect the patient and the system. Potentially unsafe situations are listed in the risk and hazard analysis covered in Appendices 16.3.A and 16.3.B.

STATEMENT OF INTENDED USE
[As Required by 21 CFR 807.92 a(5)]

Patient Population

The NanoTherm and VascuTherm devices' intended patient population is a non-ambulatory adult.

NanoTherm Indications:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.
- Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

NanoTherm Contraindications

- Presumptive evidence of congestive heart failure
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Suspected/observed patient has Raynaud's Disease
- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Patient therapy contact on extremity containing a fracture
- Extremities that are not sensitive to pain

VascuTherm Indications:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.
- Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.
- Decrease the risk of deep venous thrombosis (DVT).
- Aids the blood flow back to the heart.
- Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

- Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

VascuTherm Contraindications

- Presumptive evidence of congestive heart failure
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Suspected/observed patient has Raynaud's Disease
- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Patient therapy contact on extremity containing a fracture
- Extremities that are not sensitive to pain

The following patients must use the NanoTherm or VascuTherm therapy systems for temperature contact therapy under the supervision of a physician if they are:

- Individuals with extremities not sensitive to pain
- Individuals with extremely low blood pressure
- Individuals with Raynaud's Disease
- Hypersensitive to cold
- Children
- Diabetics

Differences in Indications

The indications for NanoTherm and VascuTherm devices are the same as those for the predicate devices listed in the Tables 1, 3 and 5 below.

TECHNOLOGICAL CHARACTERISTICS
[As Required by 21 CFR 807.92 a(6)]

The NanoTherm and VascuTherm devices have the same performance characteristics as the predicate devices.
The pneumatic control circuitry is a microprocessor-controlled system. Multiple safety redundancies are built into the system including: high and low temperature alarms, alarms for unit malfunction situations, and system malfunction overpressure safety via a pressure vent switch. Power is supplied via 110 VAC line current.
The surface contact temperature range is microprocessor controlled in cooling from 43°F to 49° and to 105°F in heating mode.

Comparison of features and principles of operation between the NanoTherm and VascuTherm devices and the predicate devices per Section 510(k) of the Act.

Table 1. Summary of Edema/Lymphedema Therapy Modality Comparison for the Units

Parameter	NanoTherm and VascuTherm for edema/lymphedema only	Chatttanooga Group, Inc. PresSsion S III (K942796)
Pump Pressure Range	30 mm Hg. ±5 mm Hg.	30-100 mm Hg. ±5 mm Hg.
Default Pressure	30 mm Hg.	User Selectable
Cycle Time	Inflation: 20 seconds Deflation: 40 seconds	Inflation: 5-120 seconds Deflation: 5-60 seconds
Indications for Use	Compression therapy is indicated for the following: Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains. (K942796)	Compression therapy is indicated for the following: Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains. Decrease the risk of deep venous thrombosis (DVT).
UL Mark	UL 60601 Class II, Type B	Class I, Type BF
CE Mark	IEC 60601-1 (safety) IEC 60601-1-1 (Emissions, Class A) IEC 60601-1-2 (Immunity)	Not known

Table 2. Summary of Edema/Lymphedema Biocompatibility Comparison for the Wraps

Parameter	Therapy wraps for edema/lymphedema only	BioCompression Systems, Inc. BioComfort Garments (K043423)
Material in Skin Contact	200 Denier Nylon Oxford	200 Denier Nylon Oxford
Sterile/Non-Sterile	Sterile and Non-Sterile	Sterile and Non-Sterile
Single Patient Use	Yes	Yes

Table 3. Summary of DVT Therapy Modality Comparison for the Unit

Parameter	VascuTherm	Chatttanooga Group, Inc. PresSsion S III (K942796)	MicroTek Medical Venodyne DVT Advantage Plus+ (K011318)	KCI PlexiPulse All-in-1 System (K981311)
Pump Pressure Range	45-100 mm Hg. ±5 mm Hg.	30-100 mm Hg. ±5 mm Hg. (calf therapy only)	40-45 mm Hg. (calf and foot therapy)	140-180 mm Hg. ±5 mm Hg. (foot therapy only)
Default Pressure	45 mm Hg. (calf) 100 mm Hg. (foot)	User Selectable	45 mm Hg.	160 mm Hg. (foot therapy only)
Cycle Time	Inflation: 30 seconds Deflation: 30 seconds	Inflation: 5-120 seconds Deflation: 5-60 seconds	Inflation: 12 seconds Deflation: 48 seconds	Inflation: 1-5 seconds Deflation 20-60 seconds
Indications for Use	Decrease the risk of deep venous thrombosis, **DVT**. (K942796, K011318, K981311) Aids the blood flow back to the heart. (K011318) Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications. (K981311)	Compression therapy is indicated for the following: Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains. Decrease the risk of deep venous thrombosis (DVT).	The Venodyne DVT Advantage model 620 is designed to compress the lower limbs aiding the blood flow back toward the heart to prevent deep vein thrombosis in patients at risk.	The Cowboy XV is intended for patients in the home who would benefit from increased blood flow to: Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant medications (medications that thin the blood), and prevent deep venous thrombosis (DVT) (blood clots in deep veins).
UL Mark	UL 60601 Class II, Type B	UL - Type BF, Class 1	Not Known	UL
CE Mark	IEC 60601-1 (safety) IEC 60601-1-1 (Emissions, Class A) IEC 60601-1-2 (Immunity)	Not Known	Yes	Not Known

Table 4.Summary of DVT Biocompatibility Comparison for the Wraps

Parameter	VascuTherm air-only therapy wraps for DVT prevention only	Aircast Vena Flow Sterile Disposable Cuffs (K023800)
Material in Skin Contact	DuPont Softesse® Medical Fabric (non-latex, non-woven)	DuPont Softesse® Medical Fabric (non-latex, non-woven)
Sterile/Non-Sterile	Non-Sterile	Non-Sterile and Sterile
Single Patient Use	Yes	Yes

Table 5. Summary of Water Circulating Thermal Therapy

Parameter	NanoTherm and VascuTherm devices	Artrotherm Cryotherapy and Thermotherapy (K964799)
Therapy Type	Heat/Cool	Heat/Cool
Therapy Temperature Range	Heat: 105°F Cold: 43°F to 49°F	Heat: 122°F Cold: 43°F
Indications for Use	Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions. (K964799)	Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2006

ThermoTek, Inc.
C/O Mr. Jay Kogoma
Senior Staff Engineer
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K061866
Trade/Device Name: NanoTherm and VascuTherm Systems
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW, ILO
Dated: August 4, 2006
Received: August 7, 2006

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061866

Device Name: NanoTherm

Indications for Use:

Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.

Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.

Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Device Name: VascuTherm

Indications for Use:

Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.

Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.

Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

Decrease the risk of deep venous thrombosis (DVT).

Aids the blood flow back to the heart.

Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061866